Extended Testimony of David M. Burns M.D.

U.S. House of Representatives
The Government Reform Committee
Hearing entitled "Potential Reduced Exposure/Reduced Risk Products: An Examination of the Possible Public Health Impact and Regulatory Challenges."
Rayburn Bldg. 2154 2:00 p.m. 6/3/03

My name is David Burns, and I am a medical doctor, professor of medicine and professor of family and preventive medicine at the University of California, San Diego School of Medicine. I was one of two scientific editors for the National Cancer Institute Smoking and Tobacco Control Monograph # 13 entitled "Risks associated with smoking cigarettes with low machine measured yields of tar and nicotine". I am also chair of the scientific advisory group for the Massachusetts Department of Health Services charged with examining the methods by which harm reduction can be evaluated, and I am on the Scientific Advisory Committee on Tobacco for the World Health Organization examining the regulation of new tobacco products. My Curriculum Vitae is attached to this testimony. My testimony today draws heavily on the deliberations of those groups and excerpts from their published reports (SACTob 2003), but I am speaking today as an individual and not as a representative of my university or of any group.

New tobacco products are being introduced for which reduced exposure, reduced toxicity, and reduced health risk claims are being made. These products include cigarettes made with modified tobacco from which established carcinogens were reduced/removed, products designed employing unconventional advanced technologies and a variety of oral tobacco products.

Evaluation of these newer products should be informed by our understanding of, and experience with, so called "light and ultralight cigarettes. Tobacco companies marketed products that claimed lower emissions (Pollay and Dewhirst 2002) but in fact, these cigarettes did not deliver reduced uptake of toxicants or lower risks to those who smoked them (Stratton et al. 2001; NCI Monograph # 13; SACTob 2002). There is no existing regulatory structure to evaluate the scientific validity of current claims for existing or modified tobacco products or to evaluate future claims (Stratton et al. 2001).

The lessons we have learned include:

1. **A simple standardized testing protocol cannot asses the exposure or risk likely to occur with different products.** Human smoking behavior changes when products with different design characteristics are smoked, whereas machines do not change their pattern of smoking in response to the changes in cigarette design. Our error in relying on tar measurement from a single protocol driven machine measurement is not that the parameters of the test were set wrong, but rather that the machine parameters that best mimic actual use are different for different styles of cigarettes. When smokers smoke ultra light cigarettes with larger more intense puffs than full flavor cigarettes, machine measurements using any single puff profile will not match the smoke delivered by these cigarettes as they are actually used by smokers.
2. **Smoke chemistry measurements may be useful to evaluate engineering changes in cigarettes or the characteristics of the smoke produced, but they are not adequate measures of actual human exposure.** Because smokers smoke different products in different ways and may respond to a given design change in an unanticipated manner, human exposure and risk can only be reliably assessed by measurements made in human smokers.
3. **Changes in risk must be evaluated for those smokers who actually use the product rather than being based simply on the characteristics of the product.** Low tar cigarettes were marketed to smokers who were thinking about quitting rather than to smokers who would not or could not quit. Even a product with real reduced toxicity in comparison to conventional cigarettes will not reduce the harm caused by smoking if it is used by those who would otherwise have quit or by those who had not previously smoked.
4. **Claims must be constrained by the data available to support them.** Because of the marketing advantages of reduced harm claims, there is great risk that the claims made will exceed the evidence to support them. For example, using evidence of changes in smoke chemistry to claim reduced exposure or reduced harm is an over statement of the actual evidence available to support the claim. The fact that it is difficult and time consuming to acquire the evidence to establish differences in exposure or reduced harm does not justify making claims for which the evidence to support them does not exist.
5. **Harm reduction cannot be adequately considered without examining the marketing messages used for the product.** Messages communicated to the consumer, the groups targeted by the marketing effort, and the proposed use of the product all define who will use a new tobacco product and how it will be used. Messages that promote initiation of tobacco use, interfere with

cessation or encourage use as a means of preserving and enhancing the level of addiction will cause harm even if the product itself is less harmful than conventional cigarettes.

6. **The meaning of a claim is defined by the understanding of the consumer not the manufacturer.** Marketing messages communicate to the consumer in a variety of ways including the words used, images presented and colors portrayed. It is the message received by the consumer from a harm reduction marketing effort that is important in determining what the consumer believes he or she is receiving when they purchase the produce and how they will use it. Methods exist to determine what consumers will comprehend from various marketing strategies and these methods should be used to prevent the delivery of marketing messages which communicate inaccurate or misleading information.
7. **Absent effective regulatory control of tobacco products, verification of manufacturer's harm reduction claims in time to prevent future consumer deception will be impossible.**

EXISTING SCIENTIFIC KNOWLEDGE

Evaluating the potential for newer tobacco products to cause/reduce harm is complex, even if real changes occur in the emission profile when they are used. Differences in human exposure and injury as well as the influence of the product on cessation and initiation all need to be included in an assessment of potential harm. Extensive reviews of the relative hazard of using existing cigarettes, and the changes in cigarettes over the past several decades, conclude that evidence does not support a difference in disease risks with the use of cigarettes with different levels of machine measured tar and nicotine yields or with product modifiers such as light or mild. (Stratton et al., 2001; NCI 2001; Canadian Expert Panel 2001; SACTob 2002). The evidence available for newer tobacco products is more limited and is largely based on chemical measurements and *in vitro* toxicity assays. The U.S. Institute of Medicine concluded that existing scientific evidence is not sufficient to allow definition of differences between newly engineered tobacco products and currently existing products for human uptake of toxicants, toxicity, or harm (Stratton et al., 2001). They also concluded that a scientific methodology to establish toxicity and harm differences for these products does not currently exist and that a structure for regulatory oversight would be essential to any scientific assessment of claims for reduced harm (Stratton et al., 2001). However, the report also concludes that emerging scientific understanding of disease mechanisms offers the promise of new and more specific methods of assessing tobacco toxicity and harm.

Product characteristics that are important in evaluating the potential for harm reduction include cigarette ingredients (particularly the type and blend of tobacco), design and engineering characteristics of the product, and elements of the manufacturing processes that may alter the ingredients used. Quantities of these ingredients by brand, and the design and manufacturing techniques used for the cigarette brand, are usually not provided by tobacco manufacturers, but they are essential for evaluation of toxicity; and they could be provided without any increased cost to the manufacturer. Patterns of actual use are also important determinants of toxicity, since they influence the delivery of toxicants to the smoker. Compensation leads smokers to use products differently based on the amount, rate and form in which nicotine is provided, making exposure extrapolation from chemical measurements even more difficult (Djordjevic et al., 1995, 2000; Kozlowski et al., 1994, 1998; Kozlowski and O'Connor 2002).

Assessment of differences in human exposure and harm is complicated by differences in the demographic characteristics and intensity of use of those who choose to use different products (Giovino et al1996; Haddock et al., 1999, NCI 2001); by the difficulty in extrapolating from forced switching studies to actual uses exposures (Benowitz 2001); by the reality that how products are marketed determines who uses the product; by what the alternatives are for the person switching to the product, and by the context in which the product is used (Ashley et al., 2001; Health Canada 2002a,b).

Perspectives On Harm Reduction

The major public health rationale for development of new or modified tobacco products is the potential for reducing the harm caused by existing tobacco products. The world health organization has suggested that the harm that may be reduced must be evaluated in at least four contexts (SACTob 2003).

Harm To The User

Harm can be examined within the narrow perspective of effects on the individuals currently using the product. Estimates of the harm reduction that can occur with shifting from one product to another are commonly derived from risk data derived from populations who are lifelong users of the different product;. for example, comparison of the risks of cigarette smokers and cigar smokers as a measure of the risk reduction that might occur if smokers switched from smoking cigarettes to smoking cigars. This approach is deeply flawed by two constraints. First, for the individual, initiation of use of a tobacco product can only increase the harm they are likely to experience in comparison with continued never use of any tobacco product; and therefore, recommending initiation with a less hazardous form of tobacco use cannot be considered a harm reduction approach. It is only the population of individuals who switch to a potentially less harmful product that can experience a reduction in harm. The difference in risk that accrues with switching from one product to another is not well estimated from the risks of those who have only used the less hazardous product. Second, smokers who switch from cigarettes to potentially less harmful products carry with them levels of addiction and patterns of use that may differ from those who have only used the less harmful product. For example, those who have only smoked cigars tend not to inhale and this difference in inhalation is felt to be responsible for much of the difference in risks of lung cancer and heart disease between those who have only smoked cigars and those who smoke cigarettes (NCI 1998). However, cigarette smokers who switch from smoking cigarettes to smoking cigars do tend to inhale eliminating much of the theoretical benefit that might be achieved from switching to smoking cigars.

Difference in toxicity with switching from cigarettes to other tobacco products should be examined by comparing those who switch to those who continue to smoke cigarettes. An alternative behavior that also needs to be part of this examination of potential harm reduction is a comparison of those who switch to those who quit using any tobacco product instead of switching. This comparison defines the maximum benefit available to the user so that the benefits of switching can be placed in appropriate context, bounded by the risks of continuing and the benefits of quitting.

For a purported harm reduction product to benefit the user who switches to it, the product must reduce the intensity of exposure to tobacco or tobacco smoke toxicants, continue that reduced intensity for a sufficient duration, and have a reduction in intensity that is sufficient to more than counterbalance the impact of an increased duration of exposure on disease risks. When estimating the differences in intensity of exposure with switching to a new product, it is necessary to account for compensatory and other changes in the actual use of the new product. For example, in some epidemiological studies the risk of lung cancer declines for smokers of lower tar cigarettes when estimated on a constant number of cigarettes smoked per day basis (Hammond 1980). However, if smokers compensate for the reduced nicotine yield by increasing the number of cigarettes they smoked per day when they switched, the risk could potentially increase.

The frequency and timing of relapse to using the previous tobacco product also need to be evaluated when considering the likelihood that reduced intensity of exposure will be of sufficient duration and magnitude to meaningfully effect disease risks. And finally, the effect of prolonging the duration of exposure needs to be considered when examining the impact of reduced intensity of exposure. Duration is a much more powerful determinant of disease risk than is intensity of smoking for cancer and lung disease (Doll and Peto 1978), and therefore modest prolongation of duration of use may overwhelm the effect of a substantial reduction in intensity of exposure in determining the risk for individual smokers.

Harm To Non-Users/By-Standers

Many new products may claim reductions in environmental tobacco smoke generation and there is clear reduction when shifting from burned tobacco products to products that heat rather than burn tobacco, or to smokeless tobacco use. However, there may be an increase in secondhand smoke exposure if individual smoking duration increases or if new products result in an increase in toxicants present in either sidestream smoke or exhaled mainstream smoke. An additional concern is the reduction in smoke emissions may be used to justify delay or reversal of restrictions on smoking in indoor environments.

Harm To The Population

The harm to the population is the net effect of the changes in harm to the individual users and the changes in number of users who are exposed. A principal concern for all harm reduction products is that their presence on the market will offer alternatives to cessation for those who are interested in quitting. If the only users of a reduced harm product are those who would have quit in the absence of the product, or if the number of smokers whose cessation is delayed or aborted by use of the product exceed the number of those who would never have quit who are using the product, then it is likely that there would be a net increase in harm to the population. This would occur even from the introduction of a product that could actually reduce the harm for those individual smokers who would not otherwise quit. Conversely, it is possible that offering harm reduction products might induce some smokers who would not otherwise have quit to use the product and then begin a path that leads to successful long-term abstinence from tobacco. These products may also play a role in enhancing the cessation success of those who are having difficulty achieving abstinence. The potential benefits described here are theoretical, as no tobacco product has currently demonstrated such benefits.

Population harm, therefore, is the net of the combined effects that harm reduction products and their marketing have on the use of tobacco products and resultant population exposure to toxicants. This calculus involves consideration of who is using the newer products and why; what the users alternative behavior might have been; whether the availability of the new product increases the initiation of tobacco use with that product; and whether, once initiated, users then transition to products with a greater degree of toxicity. These concerns cannot be addressed without considering the marketing approaches and messages utilized for harm reduction products as they are introduced in the marketplace. The experience with so called “light” and “ultralight” cigarettes is not only that their marketing messages were misleading but also that their marketing target included those who were thinking about quitting smoking (Pollay and Dewherst 2002). The risk that marketing messages may be used to intercept smokers who are on the way to cessation, or to increase the initiation of tobacco use, must be part of any estimate of the net harm produced by newer tobacco products. Monitoring of the rates of initiation and cessation are critical elements of any post-market surveillance program.

Harm Due To Marketing Messages

Messages used to market purportedly less harmful tobacco products can create harm not measured by changes in rates of tobacco initiation, use and cessation. Creation of a false perception of safety alters population norms and beliefs about tobacco, may be used by young smokers to continue tobacco use since they can switch to a safer alternative in the future, and may alter the perceived need for regulatory control of products or of smoking behavior. In addition, the offer on the market of purportedly safer products may be used by the tobacco companies as a demonstration that they have changed their corporate behavior and are now acting responsibly, even if there is no meaningful effort to actually market the products. Harm to society may accrue if these marketing messages slow the changes in social norms and the development of regulatory controls that are effective in altering tobacco use.

A Framework For Evaluating New Products

No operational regulatory model exists to adequately address the evaluation of the harm reduction claims being made for products currently on the market or for products that are likely to be introduced in the near future. There is also no scientifically validated testing protocol that would allow comparison of the injury caused by modified (reduced toxicant) cigarettes with that of older more conventional cigarette brands (Stratton et al., 2001). However, WHO has provided a scientific framework of questions that would need to be answered in examining the claims made for newer products (SACTob 2003). The questions vary somewhat for the different types of products.

Modified (reduced carcinogen/toxicant) Cigarettes

The ideal evaluation of any purported harm reduction product would be based on measures of disease outcomes from human epidemiological studies of individuals followed before and after they switched to the new product. For most disease outcomes, such studies would require very large populations followed for long intervals and could therefore only provide information on changes that occurred many years in the past. More timely examination of new products is important for both regulatory oversight and for providing accurate public health advice to consumers. The data upon which this evaluation is made will, of necessity, be more limited than that which would be available from epidemiological and other observations made over long duration of use of the new product. Limitations of the data likely to be available make it useful to conceptualize the evaluation as a set of questions that can be answered in series and which allow a progressively more complete understanding of the actual benefits likely to be experienced by those who switch to a new product. Conceptually this sequence would involve five measures: measures of smoke emissions under conditions reflecting actual use, measures of smoke uptake in actual users of the product, measures of addiction potential of the product, measures of injury from use of the product, and measures of disease outcome.

Careful independent scientific review of existing data for each of these questions allow conclusions to be drawn (and claims to be validated) for each question independently at a point in time when the data are sufficient to support the claim. The separation of the questions, and of the data to support them, will also avoid confusion about the type of claim that can be made from the data presented. For example, data on the emissions generated by a cigarette might allow claims about differences in smoke composition but would not, without measures of injury, allow claims for reduced toxicity. Allowing measures of smoke emissions (machine measured tar and nicotine yields by the FTC/ISO method, or event the Massachusetts and Health Canada methods which prescribe more intense machine smoking parameters) to be extrapolated to enable claims of reduced uptake and reduced harm (light and mild brand designators) resulted in the consumer being misled (SACTob 2002), and this experience should not be repeated with new tobacco products. If claims are to be made by the manufacturer, it should be the responsibility of the manufacturer to provide evidence supporting the claim to an independent scientific review before the claim is made. The claims must be validated by the data presented, and claims that go beyond the data presented should not be allowed. Absence of evidence, or absence of scientific methods to measure toxicity or harm, are not legitimate scientific bases to allow claims of harm reduction from measures of smoke emissions.

The first logical step in examining a product having potential to reduce the harm produced by tobacco use is to examine the characteristics of the product. Consideration of the ingredients used, both quantitatively (type and amounts of ingredients, the blend of tobacco, reconstituted sheet tobacco) and qualitatively (toxicity of burned ingredients), defines likely areas of scientific concern as does a description of the engineering design and characteristics of the product. This information is currently available to the manufacturer and can be provided at no additional cost.

The next step is to examine emissions from the product, again both quantitatively and qualitatively. There are two dimensions to this question. The first is a comparison of the emissions of a product to other products under standardized conditions, and the second is the evaluation of the emissions under conditions of actual use. Smokers may vary in the way they use a single product (Djordjevic et al., 2000), and different products may be used differently by the same smoker, making machine measured values derived using a single set of smoking conditions misleading as an estimate of the smoke emissions actually arriving at the smokers mouth when the product is used (SACTob 2002). A companion concern is quantitative and qualitative measures of second hand smoke emissions.

Smoke uptake by the smoker, rather than smoke emissions, is the measure of intensity of exposure important for predicting disease risk. Measures of uptake with actual (rather than laboratory) use of the product are key to estimating uptake for populations of individuals who are likely to use a product. As they are developed and validated, measures of the biologically effective dose (levels of toxicants in critical target organs or tissues) may offer even more precise measures of smoke uptake for predicting smoke toxicity (Stratton et al., 2001). Additional keys to assessment of differences in uptake that result from differences in actual use of different products are understanding who is using the product and why. Measures of uptake derived from comparisons of groups of users may be misleading if a large fraction of those who switch to a new product are doing so in an effort to quit or cut down the amount that they smoke. Valid comparisons of the differences in uptake attributable to differences in the products used must ensure that the populations studied are using the products with similar intentions for maintaining the intensity of their smoking behavior.

Bioassays for injury related to cancer, lung disease, heart disease, reproduction and development, or neurobehavioral systems are essential to any examination or validation of claims of reduced toxicity. At present, the evidence linking existing biomarkers to ultimate disease outcomes remains incomplete, and no biomarkers have been validated for use in distinguishing the relative injury caused by different levels of cigarette smoke uptake (Stratton et al., 2001). The potential exists for evolving scientific techniques to make a meaningful contribution to the definition of early tobacco smoke related injury, but these approaches remain future rather than current solutions. The absence of existing validated biomarkers of injury from tobacco smoke is a scientific challenge to be overcome, but the absence of measurement tools should not be used to justify claims of reduced injury or reduced harm based on smoke emission or smoke exposure data.

One of the principal harms caused by tobacco use is addiction, and evaluation of the potential to create and sustain addiction is an important component of any consideration of the potential harm that can accrue from new and modified tobacco products.

Rates of disease outcomes following tobacco use are the ultimate measure of harm from tobacco use. The long time period required to generate this information for many of the diseases caused by smoking may preclude its use in making regulatory decisions surrounding the introduction of new tobacco products, but the importance of this information to understanding the harm caused by tobacco use makes collection of this information a scientific imperative. No claim for harm reduction should be allowed in the absence of evidence demonstrating reduced harm. The length of time required to generate such data is a reality that results from the biology of disease, and it is not a justification for allowing claims in the absence of evidence.

Once products are introduced into the market, there is a continuing need to monitor who is using the products and why, changes in the product design/ingredients or marketing approaches after the product is initially evaluated, and the impact of the product on rates of smoking initiation and cessation. Who the target populations are for the marketing messages, what those target populations actually understand those marketing messages to mean, and what the effect is for populations other than the target population, are concerns requiring ongoing monitoring. Many reduced toxicant products may have the potential to either increase or decrease harm depending on who uses them and what are the alternatives to their use. Absent monitoring of these phenomena, it will likely be impossible to determine whether use of reduced toxicant cigarettes by smokers provides a benefit or a cost to the population in terms of the damage and disease caused by smoking.

Products That Allegedly Heat Instead Of Burn Tobacco.

The issues to be examined for products that use processes other than tobacco combustion to deliver nicotine are similar to those for reduced toxicant cigarettes. However, much greater attention is necessary to the technology being employed and how it functions under a variety of smoking conditions. Assumptions that these new technologies will be smoked with the same pattern of puffing as conventional cigarettes, will continue to heat rather than burn the tobacco under all of the puffing conditions likely to be encountered by consumers, or will not contain new constituents with undefined risks are not warranted and must be tested. These products may also have different potential for creating of sustaining addiction than conventional cigarettes.

Oral Tobacco Products (including smokeless tobacco, but not including NRT products already regulated for a therapeutic purpose).

Differences in the process by which tobacco constituents are delivered to the user, sites of delivery and time course of uptake make comparisons of emissions from oral tobacco products and cigarettes difficult. Even comparisons of uptake of the same constituent (e.g. nicotine) can be difficult to interpret. However, the same general concerns described above for reduced toxicant cigarettes also apply for defining the harm reduction potential of oral tobacco products. However, there are some particular concern with oral tobacco products.

It remains to be demonstrated that large numbers of adult cigarette smokers who will not otherwise quit will switch to oral tobacco products. The rate at which adults are willing to switch is important for calculating the net effect for harm reduction of marketing oral tobacco products because of the likely effects of marketing on those not yet using any tobacco product. As a new product is introduced, or an existing tobacco product is marketed as offering less risk for the smoker who is unwilling to quit, the initiation of use of that product among adolescents may increase. Existing data on current use suggests that users of oral tobacco products are much more likely to transition to cigarette smoking than are cigarette smokers to transition to smokeless products (Tomar 2002). Initiation of oral tobacco use also occurs largely among the young raising further concerns about which age groups might be influenced most by marketing messages. A real concern is that a marketing message of lower risk might not change the behavior of adult smokers but might increase the rate of adolescent initiation of oral tobacco use, increasing rather than decreasing the fraction of the population using tobacco products.

A second issue is that the data available on the risks of using oral tobacco products are derived from populations of individuals who use only oral tobacco, and little is known about the magnitude and timing of any change in risk among those who switch from smoking cigarettes to use of oral tobacco. The fraction who switch who might otherwise quit, the fraction who relapse back to smoking, the fraction who continue dual use, and the impact of dual use on disease risks are all unanswered questions in the context of offering these products as vehicles for harm reduction.

A similar concern exists for existing oral tobacco users. Will harm reduction messages reduce cessation or delay cessation attempts?

Oral tobacco products are marketed as temporary alternatives to smoking that sustain nicotine addiction in those circumstances where smoking is prohibited. The potential for these products to sustain a high level of nicotine addiction, or to otherwise reduce the interest in quitting or success in achieving abstinence, are real concerns. These effects, if present, could cause a net harm to the population even if the products themselves have low levels of toxicity.

Conclusion

In conclusion, regulatory oversight of cigarette and cigarette like products should include examination of at least five separate aspects of the new products: physical chemical characteristics of tobacco and tobacco smoke, uptake of toxicants (both by smokers and by non-smokers), toxicity, addiction potential, and disease risk. Demonstration of reductions in smoke emissions or reduced uptake of toxicants alone is not sufficient to support claims or implications of reduced toxicity or harm. No claim should be permitted for any tobacco product absent adequate scientific data. Regulatory oversight, including post market surveillance, is necessary to assess and monitor changes in newly modified tobacco products

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Consultant, Environmental Protection Agency Indoor Air Quality Advisory Committee	1990-1991
Chair, San Diego County Tobacco Control Coalition	1990-1993
Consultant, Environmental Protection Agency Science Advisory Board	1991-1995
Professor of Medicine, University of California, San Diego, School of Medicine	1991-present
Consultant, U.S. Consumer Product Safety Commission on Fire-Safe Cigarettes	1992-1993
President, American Cancer Society, San Diego Unit	1992-1993
Chair, Research Committee, American Cancer Society, California Division	1993-1994
Committee Member, Evaluation Advisory Committee, Tobacco Control Section, California Department of Health Services	1992-present
Board Member, Tobacco Education and Research Oversight Committee, California Department of Health Services	1997-2001
Committee Member, Surveillance Implementation Group, National Cancer Institute	1998-1999
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AWARDS

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Alton Oschner Award	2002

PUBLICATIONS

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